

## DETAILED ACTION

Applicant's response filed on 02/08/2011 in response to office action mailed on 11/08/2010 has been acknowledged.

Claims 5, 17, 28, 33, 34, and 37 are amended.

Claims 9, 18-20, 35, 36 and 40-48 are canceled.

Claims 1-4, 6-8, 10-16, 21-27, and 29-32 were previously canceled.

*Claims 5, 17, 28, 33-34 and 37-39 are pending and are examined in this office action.*

*Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.*

Withdrawn: Claim 9 rejection under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record as set forth in the office action mailed on 11/08/2010 is withdrawn in view of cancellation of the cited claim..

Withdrawn: Claims 5, 9, 17-20, 28 and 33-48 rejections under 35 U.S.C. 112, first paragraph (scope of enablement) for the reasons of record as set forth in the office action mailed on 11/08/2010 is withdrawn in view of Applicants amendments to claims obviating the rejections..

Withdrawn: Claims 9, 43-48 a rejections under 35 U.S.C. 103(a) as being unpatentable over Capecci (U.S. Pat. No.5, 464,764; art of record) in view of Seth et al.,(2000, Biochemical and Biophysical Research communications 241: 535-540; art of record) for the reasons of record as set forth in the office action mailed on 11/08/2010 is withdrawn in view of Applicants amendments to claims obviating the rejections..

## Claim Objections

Claim 5 is objected-to as it recites on line 3 "that comprises" instead of reciting for example "wherein the transgene comprises". As currently written it implies that the endogenous Sigma-receptor gene comprises a selection marker and is incorrect.

Claim 17 is objected to for not further limiting, as it does not require the mouse but the offspring because it reads on a cell from a non-mutant mouse, because "offspring" includes crosses with wild-type mice, and many subsequent generations.

Claim 33 is objected to for reciting on line 3 " disrupts the endogenous Sigma-1 receptor". Disruption is in the gene not the protein. Instead use of a phrase such as "endogenous Sigma-1 receptor gene" is preferable.

Claims 5, 17, 28, 34 and 37-39 are objected to for depending directly or indirectly from claim 33.

Claim 34 is objected-to as it recites on line 3 "to insert a functional disruption in endogenous Sigma-1 receptor...." Instead it should recite for example "to insert a functional disruption in to the endogenous Sigma-1 receptor gene....". The vector only disrupts the gene.

Claim 38 is objected-to as it recites on line 3 "that comprises gene encoding...." . Instead it should of recite as for example "wherein the transgene comprises sequence encoding...". As currently written it implies that the endogenous Sigma-receptor gene comprises the genes for selection marker and is incorrect.

### Double Patenting Warning

Applicant is advised that should claim 33 be found allowable, claim 37 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The transgenic mutant mouse of claim 37 and 33 refer to the

same product "homozygous mutant mouse deficient in endogenous Sigma-1 receptor" product having the same structure and properties, therefore, despite a slight difference in wording, Claim 37 is a substantial duplicate of Claim 33.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 17, 28, 33-34 and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim 33 recitation on line 3 of "disrupts the endogenous Sigma-1 receptor" makes the claim vague and indefinite. Use of a phrase such as "endogenous Sigma-1 receptor gene" instead would overcome the rejection.

Claims 5, 17, 28, 34 and 37-39 are rejected as they depend directly or indirectly from claim 33.

Claim 39 recitation of "the neomycin...gene" has no antecedent basis.

### ***Conclusion:***

No claim allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna Ph.D.*, whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.*, may be reached at **(571) 272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

/ROBERT M KELLY/  
Primary Examiner, Art Unit 1633